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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

ILLUMINA, INC. and ILLUMINA CAMBRIDGE LTD.,

Plaintiffs,

v.

COMPLETE GENOMICS, INC.,

Defendant.

Case No. 3:12-cv-01465-BEN-BGS

ILLUMINA'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

Hon. Roger T. Benitez
Date: July 18, 2013
Time: 9:00 A.M.
Room: 5A

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I. Introduction

The Court should reject CGI's proposed constructions because they violate two fundamental rules of claim construction: CGI improperly limits Claim 1 to cover only the specification's preferred embodiments, and improperly reads limitations from Claim 2 into Claim 1 so as to render the two claims identical.

CGI ignores the express language of Claim 1 and instead construes Claim 1 to cover only preferred embodiments described in the specification. And although the specification recites all of the elements of Claim 2 in the "Summary of the Invention" section, Claim 1 should not be construed to contain all of those elements. The claims, not the specification, define the patent right. The Court should not render Claim 1 meaningless by construing it to be the same as Claim 2.

CGI also says the specification does not support Claim 1 as written because the specification requires a specific method of reading sequence information. That is simply untrue. Contrary to CGI's assertion, the specification expressly states that the invention is *not* limited to using any particular sequencing method.

II. CGI's factual background misleads and omits important facts

CGI makes several misleading statements and omissions in its factual background. First, CGI says that extensive technical background about DNA structure, amplification, and sequencing is important to give context to "the most significant terms in this dispute." (CGI Br. at 1:15–22.) But CGI omits from its factual background any information about sequencing-by-ligation: a sequencing technique expressly disclosed in the '930 patent and which CGI uses in its accused Combinatorial Probe Anchor-Ligation ("cPAL") technology. CGI ignores sequencing-by-ligation

completely and tries to create non-infringement arguments by proposing constructions that exclude its sequencing-by-ligation technology from the scope of Claim 1. In contrast, we explained sequencing-by-ligation in our opening brief because the '930 patent expressly says that it is a method of reading sequence information that can be used in the invention. (Exh. A at 22:9–17.)

Second, CGI claims it will "prevail" "[n]o matter which constructions the Court adopts." (CGI Br. at 1–2 n.2.) However, CGI effectively concedes that under Illumina's constructions, CGI infringes Claim 1: CGI says that under its constructions, "CGI does not infringe," but under Illumina's constructions, CGI says only that "Claim 1 is invalid over the prior art." (*Id.*) In any event, CGI is wrong on both points: under Illumina's proposed constructions, CGI infringes, and Claim 1 is valid.

Third, CGI asserts that "[p]airwise sequencing is an old method" and that the invention of Claim 1 "must be something more than the mere concept of pairwise sequencing." (CGI Br. at 6:18, 7:20–22.) A plain reading of Claim 1—without adding further limitations into the claim as CGI proposes—shows that it requires more than the "mere concept of pairwise sequencing." It is a novel method of pairwise sequencing because it includes all of the steps recited in the claim. This is why the Patent Office granted the '930 patent to Illumina. (Exh. F, Apr. 2, 2012 Notice of Allowance at 2–3.)

III. Argument

CGI's constructions ignore the "'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari*

Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Instead, CGI proposes limiting Claim 1 to the embodiments described in the "Summary of the Invention" section of the specification. This is incorrect as a matter of law. *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("The claims, not specification embodiments, define the scope of patent protection.").

A. "in the same target double stranded polynucleotide"[1]

1. The claim and specification support Illumina's construction

CGI's argument that Claim 1 requires both strands of a "template polynucleotide duplex" to be "linked to the solid support at or near their 5' ends" ignores the express language of Claim 1. The claim does not say anything about a solid support, and CGI's arguments do not justify adding that limitation to the claim.

First, CGI says that Illumina's construction is "strained" and "divorced from the teachings of the patent." (CGI Br. at 12:11–12, 17:23–24.) It is not: the specification supports Illumina's construction. In Claim 1, the phrase "same target double stranded polynucleotide" describes the polynucleotide in which the "first and second regions" for obtaining sequence information are located. As explained in our opening brief, those first and second regions must be *single-stranded* at the time of sequencing, which CGI does not dispute. (Illumina Op. Br. at 13:3–22.)

According to the claim, those two single-stranded regions are derived from the same original double-stranded polynucleotide. In other words, Claim 1 says the target polynucleotide is double-stranded because the two regions are on either the same strand *or* on the complementary

[1] In our opening brief, we addressed the claim terms in the order they appear in Claim 1. In this responsive brief, we will address the claim terms in the order CGI addressed them in its opening brief.

strands of that target—which CGI also does not dispute. (Exh. A at 5:54–57.) Unlike CGI's construction, Illumina's construction explains the term "same target double stranded polynucleotide" without importing any additional limitations into Claim 1 and is consistent with the specification.

Second, CGI argues that Illumina's construction is too broad because it would cover "any" DNA or "even RNA." (CGI Br. at 12:12–15, 17:17–23.) However, the specification supports a broad interpretation: "[t]he target nucleic acid may be essentially any nucleic acid of known or unknown sequence. It may be, for example, a fragment of genomic DNA or cDNA," and "the method may also be applied to ribonucleic acid (RNA)." (Exh. A at 6:60–63, 7:5–7.)

Third, CGI argues that Illumina's construction must be wrong because in the specification, "original polynucleotide duplex" always refers to an immobilized duplex. (CGI Br. at 18:9–17.) But CGI cites only preferred embodiments, which do not limit the claim, such as where CGI cites the statement in the specification that "*[i]n one embodiment*, both strands of the original polynucleotide duplex remain immobilized." (CGI Br. at 18:14; Exh. A at 3:64–67 (emphasis added).)

2. CGI's construction excludes a preferred embodiment

CGI's construction is also incorrect because it excludes the third preferred embodiment described in the "Summary of the Invention" section of the specification. As CGI acknowledged in its opening brief, this embodiment includes removing one strand from the solid support to provide a single-stranded polynucleotide. The first and second primers are then hybridized and read from the remaining single-stranded polynucleotide. (CGI Br. at 9:7–10; Exh. A at 4:21–24.)

CGI construes "same target double stranded polynucleotide" to require that both strands of the double-stranded polynucleotide are attached to a support when hybridizing the second primer. Claim 1 recites that the "second primer" hybridizes to a "different location" in "the same target double stranded polynucleotide." CGI's construction therefore requires that both strands are attached to the support when the second primer hybridizes to a "different location" in "the same target double stranded polynucleotide." But in the third preferred embodiment, only one strand of the polynucleotide remains, so under CGI's construction, the second primer could never hybridize to a "different location" in "the same target double stranded polynucleotide."

CGI's construction requires that both strands are attached when the second primer hybridizes. This excludes the third embodiment in the Summary of the Invention, which removes one strand from the support before hybridizing the second primer. CGI's construction therefore must be incorrect. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (noting that a construction that excludes a preferred embodiment "is rarely, if ever, correct").

3. Claim 1 is broader than the preferred embodiments, and there was no disclaimer of scope

CGI asks this Court to limit Claim 1 to cover only the embodiments described in the specification. That would be legal error: if the claim as written is broader than the embodiments, the Court cannot limit the claim to cover only the embodiments unless the patentee demonstrated a "clear intent" to limit the claim scope in that manner. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906–07 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has

demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'") (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)).

CGI argues that the Court should import limitations from the specification into Claim 1 because those limitations appear in the "Summary of the Invention" preceded by the phrase "according to the invention." (CGI Br. at 13:1–17.) As cases like *Liebel-Flarsheim* show, if the claims are broader than the embodiments, even limitations described in the specification as part of "the invention" do not limit the claims unless the patentee demonstrated a "clear intent" to limit the claim scope in that manner.

In *Liebel-Flarsheim*, the district court construed the claim term "injector" to require a "pressure jacket" (a term not mentioned in the claim) because the abstract, *every* embodiment, *and* the Summary of the Invention described "the invention" as including a pressure jacket. 358 F.3d at 908. The Summary of the Invention said that "According to the principles of the present invention, there is provided an angiographic injector having a front end loadable syringe that can be loaded into and removed from the injector pressure jacket through an opening that is provided in the front end of the pressure jacket." *Id.*

The Federal Circuit reversed, holding that a pressure jacket was *not* a required element of the claimed invention: "Absent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that the scope of the invention is limited to that context." *Id.* at 909 (quoting *Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1355 (Fed. Cir. 2003)).

Here, as in *Liebel-Flarsheim*, where the claim was not limited to require a pressure jacket even though the Summary of the Invention referred to a "pressure jacket" as part of "the principles of the present invention," the fact that the '930 patent inventors anticipated that their invention could be used with immobilized polynucleotides attached at their 5' ends does not limit the scope of Claim 1 to that embodiment, absent a "clear disclaimer." *Liebel-Flarsheim*, 358 F.3d at 909.

A "clear disclaimer" can include, for example, criticism of features that would be included under a broad construction coupled with a statement that the limitation is used in "all embodiments of the present invention *contemplated and disclosed* herein." *Id.* at 906–07 (emphasis added) (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1344 (Fed. Cir. 2001)).

CGI has not identified a clear disclaimer of claim scope in the '930 specification. As we explained in our opening brief, the '930 specification contains no such disclaimer. To the contrary, it expressly contemplates alternative embodiments that would be excluded by CGI's proposed construction. (Illumina Op. Br. at 16:20–17:23.) For example, the Summary of the Invention says that the "inventors have developed a method for . . . sequencing of double-stranded polynucleotide templates, *including* double-stranded templates present on clustered arrays, such as those described herein." (Exh. A at 3:20–23 (emphasis added).) But the patent never says the method is *limited* to double-stranded templates on clustered arrays.

The cases CGI cites to support limiting Claim 1 to the embodiments described in the Summary of the Invention are different than the facts here. Attaching a double-stranded polynucleotide to a solid support is *not*

required by "clear implication of the claim language." *Gaus v. Conair Corp.*, 363 F.3d 1284, 1288 (Fed. Cir. 2004). Nor does the Summary of the Invention describe attachment to a solid support as necessary to accomplish the "general object of the present invention." *Morvil Technology, LLC v. Medtronic Ablation Frontiers, LLC*, 2012 WL 3277272, at *16 (S.D. Cal. Aug. 10, 2012). And the '930 patent does not define the phrase "in the same target double stranded polynucleotide," much less "explicitly define" it as being attached to a solid support. *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004) (limiting claim where term "plug" was "defined globally as requiring a pleated surface").

4. CGI's argument violates the doctrine of claim differentiation, calling for Claim 1 to be the same as Claim 2

CGI argues that Claim 1 must be limited to embodiments described in the Summary of the Invention. (CGI Br. at 13:1–17.) This would require the Court to construe Claim 1 to be exactly the same as Claim 2. In the '930 patent, the Summary of the Invention recites *all* of the elements of Claim 2 (*i.e.*, steps (a) through (g)). (Exh. A at 3:32–63.) Therefore, if Claim 1 is limited to the elements listed in the Summary of the Invention, Claim 1 would be exactly the same as Claim 2. The Court should not incorporate those limitations into Claim 1 because doing so would violate the presumption of claim differentiation. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc). (*See also* Illumina Op. Br. at 17:24–18:7.)

5. The prosecution history supports Illumina's construction, not CGI's

CGI contends that the prosecution history "undermines" Illumina's construction because when Illumina filed a preliminary amendment to

add Claim 1, Illumina only cited Claim 2 for support. This is not true. In fact, Illumina said that support for Claim 1 (application claim 27) "is found *throughout the specification* and in the original claims." ((Exh. G, Aug. 7, 2008 Preliminary Amendment at 8.)

Rather than undermine Illumina's construction, the preliminary amendment actually supports that construction. Illumina's preliminary amendment adding Claim 1 is evidence that Claim 1 does ***not*** require attachment of the polynucleotide to a surface. Illumina added Claim 1 of the '930 patent (application claim 27), which does ***not*** require the polynucleotide to be immobilized or attached, when all of the other claims required the polynucleotide to be either "immobilized" or "attached" to a surface. (Exh. G at 3–7.) This amendment adding a claim that does ***not*** require attachment is a "strong indication that the applicants intended" the added Claim 1 to ***not*** require attachment. *Liebel-Flarsheim*, 358 F.3d at 909 (amendment of claims during prosecution was evidence of intention to omit claim elements).

Finally, as explained in our opening brief, *both* the examiner's treatment of Claim 1 and Illumina's statements throughout prosecution are further evidence that Claim 1 does not require attachment of the polynucleotide to a solid support. (Illumina Op. Br. at 18:8–19:18.)

6. Attachment to a solid support is not "crucial" to claim 1

CGI claims that the "purpose" of the invention "drives the attachment requirement," which is "crucial to the invention." (CGI Br. at 15:11–16.) CGI's assertion that "the invention would not work" without "both strands attached to the solid support" is merely attorney argument. (*Id.* at 15:15–16.) As discussed above, it is inconsistent with the third embodiment described in the Summary of the Invention, where one of the

two strands is removed before reading and hybridizing. (Exh. A at 4:16–24.) Therefore, the "strands" need not "survive denaturation and remain bound to solid support" as CGI contends. (CGI Br. at 15:21–22.)

The "purpose" of the invention is to obtain two reads of sequence information according to the steps set forth in Claim 1. The purpose is *not* to bind DNA to a solid support. In contrast to CGI's unsupported attorney argument, the examiner at the Patent Office understood that Claim 1 does ***not*** require attachment to a solid support. (Illumina Op. Br. at 18:8–19:18.)[2]

7. The testimony of the inventors adds nothing to CGI's argument

CGI relies on inventor testimony to explain the preferred embodiments described in the Summary of the Invention. (CGI Br. at 15:25–17:10.) But in this testimony, the inventors simply reiterated what the specification says about those embodiments; their testimony was not about the proper scope of Claim 1 (which in any event is a legal question for the Court, not the inventors). *Howmedica Osteonics Corp. v. Wright Med. Tech.*, 540 F.3d 1337, 1347 (Fed. Cir. 2008) (inventors are not qualified to testify about the scope of claims).

B. "reading from a [first/second] primer"

1. CGI disregards the specification

CGI's argument that "reading" requires sequencing-by-synthesis directly contradicts the express statement in the specification that the

[2] To the extent CGI argues that Claim 1 would be invalid under Illumina's construction, this is not a proper inquiry for claim construction. The issue now is the proper construction of the terms in Claim 1. The question is not whether the claim, properly construed, is enabled or has sufficient written descriptive support. That is an issue for the Court to decide later, if CGI challenges the validity of Claim 1 after the Court construes the claim.

"methods of the invention ***are not limited to*** use of the sequencing method [sequencing-by-synthesis] outlined above." (Exh. A at 22:9–10 (emphasis added).) Instead, the methods of the invention "can be used in conjunction with essentially any sequencing methodology which relies on successive incorporation of nucleotides into a polynucleotide chain." (*Id.* at 22:10–13.) "Suitable techniques include, for example, Pyrosequencing™, FISSEQ . . ., MPSS . . . and ***sequencing by ligation***-based methods, for example as described in U.S. Pat. No. 6,306,597." (*Id.* at 22:13–17 (emphasis added).) (*See also* Illumina Op. Br. at 20:26–22:2.)

2. Illumina's construction is not ambiguous

CGI argues that the term "near" is "impermissibly vague." (CGI Br. at 22:25.) It is not. Rather, "near" will explain to the jury what it means to read "from" a primer. Although CGI criticizes Illumina's construction, CGI makes no effort to define what "from" a primer means, instead using the term "from" in its proposed construction. Illumina's proposed construction is necessary because the jury may not understand what it means to read sequencing information "from" a primer.

CGI argues that "reading from" means that "[n]ucleotides are added directly *into* the primer," (CGI Br. at 23:7–9), and that the nature of each nucleotide is determined after each incorporation (CGI Br. at 19:3–6). The specification, however, teaches that every base need not be determined, and determining the identity of every base after incorporation is not required. According to the '930 patent, the bases to be read "do not, however, need to be contiguous, nor does every base on the entire fragment have to be sequenced." (Exh. A at 6:46–48.) In other words, the specification does not require determining the identity of the base immediately contiguous to the primer, or every base adjacent to the primer. And reading does not require "determination of the nature of the

nucleotide after each incorporation," a step which the specification refers to as merely a "particular embodiment." (Exh. A at 21:36–38.) Thus, "reading from a primer" only means sequence information must be obtained near the primer.

In view of these teachings in the specification, "near" will help the jury understand the claim term, while not incorporating unwarranted limitations into the claim. *See Young v. Lumenis, Inc.*, 492 F.3d 1336, 1346 (Fed. Cir. 2007) (finding "near" to be sufficiently definite where a person of ordinary skill would understand the term).

In view of the specification, a person of ordinary skill in the art would understand what "obtaining sequence information near where the primer has hybridized" means. Although reading is not limited to any particular method of obtaining sequence information, all of the methods identified in the specification were previously known methods of reading sequence information that a person of ordinary skill would understand. (Exh. A at 22:13–17.) Because these methods do not necessarily determine the nature of every nucleotide adjacent to the primer, the term "near" the primer properly defines the scope of the claim.

C. The Court should not construe "removing the first primer"

The jury will understand what "removing the first primer" means without any construction of the phrase. CGI's proposal that "removing" means "denaturing" will only confuse the jury by substituting a scientific term in place of a common word. CGI says that its construction of "removing" includes both the "means of removal" and the "timing of removal." (CGI Br. at 24:11–12.) But "removing the first primer" implies nothing about the means or timing of removal. Instead, CGI once again attempts to add limitations into Claim 1 that are not in the claim.

CGI asserts that "a patentee cannot avoid defining its own claim

term by asserting only that its term has a plain meaning." (CGI Br. at 25:12–13.) CGI cites virtually no authority for this proposition. The first case CGI cites addresses a show-cause order where both parties failed to follow the court's order regarding the claim-construction process. *Liebel-Flarsheim Co. v. Medrad Inc.*, 2006 WL 335846, at *6 (S.D. Ohio Feb. 14, 2006). The second "case" CGI cites is not an opinion at all, but rather the claim-construction brief of a patent-infringement defendant that itself does not cite any authority. *Ronald A. Smith & Assocs. v. Hutchinson Tech. Inc.*, 2002 WL 34691122, at *1 (N.D. Cal. Aug. 16, 2002) (memorandum of law).

In contrast, we cited two district court cases in our opening brief where courts (including this Court) refused to construe claim terms because the terms had a plain-and-ordinary meaning. (Illumina's Op. Br. at 22:18–24.) And the Federal Circuit has routinely held that courts should not construe every claim term where the terms have a plain-and-ordinary meaning the jury will readily understand. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1367–68 (Fed. Cir. 2012) (reversing district court's construction of "attached" because it "should be given its plain and ordinary meaning"); *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1206–07 (Fed. Cir. 2010) (declining to construe "addressed to a client" and instead adopting its "plain and ordinary meaning").

D. "first and second regions"

1. CGI attempts to construe "first and second regions" to include overlapping regions

The parties dispute whether "first and second regions" must be merely "distinct" or "distinct and separate." In its brief, CGI says that "distinct" is the correct construction because that term encompasses

overlapping regions. CGI cites little support for its counterintuitive argument that "distinct" regions can overlap.

CGI says only that the Abstract refers to the two regions as "distinct and separate." In fact, this phrase appears twice in the patent, both in the Abstract and in the Field of the Invention. (Exh. A at Abstract & 1:22.) The specification also explains that the two regions are separate: "The method provides . . . two regions of sequence . . . linked within a certain distance of each other." (Exh. A at 22:30–34.) This description makes clear that the two regions are separate.

Nothing in the specification says the two regions can overlap, undermining CGI's argument that the Abstract "contradicts the entirety of the specification." (CGI Br. at 28:10.) Instead, the specification is consistent with the two regions being distinct and separate. CGI points to Figure 1 to argue that the two regions could, in theory, overlap, but fails to cite any embodiment described in the specification where the regions do overlap. Figure 1 does not illustrate overlapping regions. The fact that the polynucleotide to be sequenced may be between 50 and *1500* base pairs (Exh. A at 7:61) does not mean that two reads of 25 bases, from primers of 10 bases, will overlap.

Finally, the testimony of Dr. Barnes is irrelevant. (CGI Br. at 27 n.12.) Dr. Barnes did not testify about the meaning of Claim 1, but rather "pairwise" sequencing generally. Moments after giving the testimony CGI cites, Dr. Barnes testified that if reads overlap, they are *not* paired reads. (Exh. H at 118:13–16.) In any event, inventor testimony should be accorded little weight because, as in this instance, inventors are not qualified to testify to "the ultimate scope of the claims . . . after allowance by the PTO." *Howmedica Osteonics Corp. v. Wright Med. Tech.*, 540 F.3d 1337, 1347 (Fed. Cir. 2008).

2. Illumina agrees that the first and second regions may be on the same or complementary strands

Illumina agrees that the first and second regions may be on the same or complementary strands of the target double-stranded polynucleotide. However, Illumina incorporates this concept as part of its construction of "in the same target double stranded polynucleotide," where it belongs. The phrase "first and second regions" should be construed to mean "two distinct and separate single-stranded portions." The language in the claim following that phrase requires additional construction to make clear the location: the two regions in the target double-stranded polynucleotide may be on the same or complementary strands of that polynucleotide. But that restriction applies to "in the same target double stranded polynucleotide," not the phrase "first and second regions."

E. Illumina's construction of "different location" makes clear what occurs at a "different location"

CGI merely makes the same argument regarding "different location" as it does regarding "first and second regions." The Court should adopt Illumina's construction because it makes clear what occurs at a "different location." This is explained in more detail in our opening brief. (Illumina Op. Br. at 24:1–25:15.)

IV. Conclusion

For all of the foregoing reasons, the Court should adopt Illumina's proposed claim constructions.

Dated: June 12, 2013

Respectfully submitted,
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